UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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| KERYX BIOPHARMACEUTICALS, INC.,<br>Plaintiff,<br><br>-against-<br>PANION & BF BIOTECH, INC.,<br>Defendant. | ECF CASE<br>**DEFENDANT'S ANSWER AND COUNTERCLAIMS**<br><br>CIVIL ACTION NO. 07 CV. 10376 (CSH) |

Defendant Panion & BF Biotech, Inc. ("Panion") responds to Plaintiff's First Amended Complaint as follows:

## NATURE OF THE ACTION

1. States that the complaint speaks for itself with regard to the nature of the action, admits that Panion notified Keryx that Keryx was in breach of the License Agreement, and denies all other allegations of paragraph 1 of the Complaint except that there is a licensing agreement with limitations to the contractual rights of Keryx Biopharmaceuticals, Inc. ("Keryx").

## PARTIES AND JURISDICTION

2. States that the complaint speaks for itself, but if an answer is required, Defendant denies having sufficient information or knowledge to form a belief as to the truth of paragraph 2 of the Complaint.

3. Admitted.

4. States that the complaint speaks for itself, but if an answer is required, Defendant denies having sufficient information or knowledge to form a belief as to the truth of paragraph 4 of the Complaint.

5. Admits that the parties are of diverse citizenship but Defendant lacks sufficient knowledge to admit or deny the remaining allegations of paragraph 5 of the complaint.

6. Admits that venue is proper pursuant to 28 U.S.C. § 1391(a).

**BACKGROUND**

7. States that Defendant lacks sufficient information or knowledge to admit or deny the allegations of paragraph 7 of the Complaint.

8. Admits the allegations of paragraph 8 of the Complaint except that the U.S. Patent is not "U.S. Patent No. 5,7753,706," but is U.S. Patent No. 5,753,706.

9. Admitted, except denies that the territory "covers most of the world" in that rights were not granted for China, Korea, and all other countries in the Asia Pacific Region, excepting Japan.

10. Admitted.

11. Admitted.

12. Admitted.

13. Denies allegations of sentence 1 of paragraph 13 of the Complaint. Admits allegations of sentence 2 of paragraph 13 of the Complaint.

14. Admits receipt of July 26, 2006 e-mail. Admits that Panion introduced Keryx to BRI Biopharmaceutical Research, Inc. ("BRI"), but denies that BRI was only Panion's "previous contractor," and denies that the introduction was "for the purposes of organizing supply". Admits that Panion was invited to attend a meeting with BRI and Keryx but denies inference that

the meeting was to discuss supply of API. Admits that Panion communicated that "Panion is a small company with limited budget and resources," and state upon information and belief that the meetings were not for the purposes of organizing supply, as implied in the complaint. Denies all other allegations of paragraph 14.

15. Admitted.

16. States that Defendant lacks sufficient information or knowledge to admit or deny knowledge of the circumstances of introduction of Keryx to BioVectra DCL or to the PharmPro Services division of Fluid Air, Inc. Admits that a quotation was emailed to Keryx, with a copy to Panion, on August 24, 2006. States that with respect to the Keryx's placement of a purchase order with BioVectra on September 5, 2006, the Complaint speaks for itself. States that Defendant lacks sufficient information or knowledge to admit or deny whether the manufacture of 400 kg of ferric citrate was placed under said quotation.

17. Admits allegations in sentence 1 of paragraph 17. States that Defendant lacks sufficient information or knowledge to admit or deny the allegations of sentence 2 of paragraph 17 of the Complaint. States that the Defendant lacks sufficient information or knowledge to admit or deny the allegations in sentence 3 of the Complaint. States that Defendant lacks sufficient information or knowledge to admit or deny the allegations of sentence 4 of paragraph 17 of the Complaint. Denies the allegations of sentence 5 of paragraph 17 of the Complaint because Panion could not voice objection without awareness. Admits the allegations of sentence 6 of paragraph 17 of the Complaint. States that the Defendant lacks sufficient information or knowledge to admit or deny the allegations of sentence 7 of the paragraph 17 of the Complaint.

18. States that Defendant lacks sufficient information or knowledge to admit or deny the allegations of sentence 1 of paragraph 18 of the Complaint. Denies the allegations of

sentence 2 of paragraph 18 of the Complaint. Denies the allegations of sentence 3 of paragraph 18 of the Complaint. Admits the allegation of sentence 4 of paragraph 18 of the Complaint. Admits the allegations of sentence 5 of paragraph 18 of the Complaint. Denies the allegations of sentence 6 of paragraph 18 of the Complaint. States that the Defendant lacks sufficient information or knowledge to admit or deny the allegations of sentence 7 of paragraph 18 of the Complaint. States that Defendant lacks sufficient information or knowledge to admit or deny the allegations of sentence 8 of paragraph 18 of the Complaint. Admits the allegations of sentence 9 of paragraph 18 of the Complaint. Admit allegations of sentence 10 of paragraph 18 of the Complaint. Admits receipt of the batch records and Certificates of Analysis, but denies approval of specifications in sentence 11 of paragraph 18 of the Complaint. Admits the allegations in sentence 12 of paragraph 18 of the Complaint.

19. States that Defendant lacks sufficient information or knowledge to admit or deny the allegations in paragraph 19 of the Complaint because the information is within the purview of the Plaintiff.

20. Denies that Panion has "repeatedly sought to share in that initial payment," states that the remainder of the paragraph speaks for itself, but if an answer is required, Defendant denies having sufficient information or knowledge to form a belief as to the truth of the remainder of paragraph 20 of the Complaint.

21. Admitted.

22. Admitted.

23. Admitted.

24. Admitted.

25. Admitted.

**FIRST CAUSE OF ACTION**
**(Breach of contract)**

26. In response to paragraph 26, Defendant repeats and re-alleges Defendant's responses to paragraphs 1-25 of the complaint as though fully set forth herein.

27. Admitted.

28. Denied.

29. Denied.

**SECOND CAUSE OF ACTION**
**(Tortious interference with contractual relations)**

30. In response to paragraph 30, Defendant repeats and re-alleges Defendant's responses to paragraphs 1-29 of the complaint as though fully set forth herein.

31. Denied.

32. Denied.

33. Denied.

**THIRD CAUSE OF ACTION**
**(Declaratory judgment that Keryx has not breached the License Agreement)**

34. In response to paragraph 34, Defendant repeats and re-alleges Defendant's responses to paragraphs 1-33 of the complaint as though fully set forth herein.

35. Denied.

36. Denied.

37. Denied.

38. Admitted.

**FOURTH CAUSE OF ACTION**
**(Anticipatory breach)**

39. In response to paragraph 39, Defendant repeats and re-alleges Defendant's responses to paragraphs 1-38 of the complaint as though fully set forth herein.

40. Admitted.

41. Admits the statement in the notice dated October 31, 2007 and denies breach of termination clause.

42. Denied.

43. Denied.

**FIFTH CAUSE OF ACTION**
**(Breach of contract)**

44. In response to paragraph 44, Defendant repeats and re-alleges Defendant's responses to paragraphs 1-43 of the complaint as though fully set forth herein.

45. Admitted except to state that Section 8.1.1 of the License Agreement is not recited in its entirety by Plaintiff, adding that the first sentence of provision 8.1.1 states in its entirety, "Licensor shall use reasonable efforts to prosecute the patent applications included in the Patent Rights, (subject to the provisions of Section 8.1.2(d) to obtain patents thereon, to conduct any interference, re-examination, reissue and opposition proceedings, and to maintain patents included in the Patent Rights in effect during the term of this Agreement using outside patent counsel acceptable to Licensor.)" and adding that the sentence following the segment quoted by Plaintiff states, "Licensee agrees that all final decisions regarding the preparation and prosecution of such patent applications and patents, reissues, reexaminations, interferences and oppositions relating thereto shall be made by Licensor after consultation with Licensee."

46. Denied.

47. Admits issuance of second Japanese Office Action on August 28, 2007. Admits the allegations of sentence 2 of paragraph 47. Denies that docket reports sent by Panion to Keryx were incorrect and misleading because Panion's Japanese patent counsel only reported the issuance of the second Japanese Office Action (in the Japanese language) to Panion's U.S. patent

counsel on September 11, 2007, and therefore Panion could not have included such information in the September 5, 2007 docket report, nor did Panion intentionally omit the information from the September 21, 2007 docket report which had only recently been provided to Panion in an English-language form.

48. Admits permitting Japanese patent counsel to collaborate with the patent counsel of Japan Tobacco, but deny that the purpose was to evaluate the Notice of Office Action or to determine how to prepare a response, because the response had been drafted by Panion's domestic patent counsel, and states that the collaboration was to perform and evaluate prior art searches, at Keryx's insistence, ostensibly intended to buoy the draft response. Denies the allegations of sentence 2 of paragraph 48 of the Complaint. Admits the allegations of sentence 3 of paragraph 48 of the Complaint.

49. Admitted.

50. Admitted.

51. Admitted, except state that the Defendant lacks sufficient information or knowledge to admit or deny the allegations of sentence 1 of paragraph 51 of the Complaint regarding alleged "pressure of time".

52. Denied.

53. Denied.

**SIXTH CAUSE OF ACTION**
**(Breach of implied covenant of good faith and fair dealing)**

54. In response to paragraph 54, Defendant repeats and re-alleges Defendant's responses to paragraphs 1-54 of the complaint as though fully set forth herein.

55. Admitted.

56. Denied.

57. Denied.

58. Denied.

59. Denied.

## AFFIRMATIVE DEFENSES

### FIRST DEFENSE
### (Failure to State a Claim)

60. The complaint fails to state a cause of action upon which relief may be granted.

### SECOND DEFENSE
### (Unclean Hands)

61. Keryx's claims are barred by the equitable doctrine of unclean hands.

### THIRD DEFENSE
### (License, Consent, Waiver, Laches, Estoppel)

62. Keryx's claims are barred by license, consent, waiver, laches, and estoppel.

### FOURTH DEFENSE
### (Failure to Mitigate Damages)

63. Keryx's claims are barred by reason of plaintiff's failure to mitigate damages.

### FIFTH DEFENSE
### (Statute of Frauds)

64. Keryx's claims are barred by the Statute of Frauds.

### SIXTH DEFENSE
### (Lack of Justiciable Controversy)

65. There is no justiciable controversy with respect to Keryx's claims.

## COUNTERCLAIMS

66. Counterclaimant Panion & BF Biotech, Inc. ("Panion") hereby alleges as follows:

## PARTIES

67. Counterclaimant Panion is a corporation incorporated under the laws of Taiwan, People's Republic of China, and has its principal place of business therein, at 16F No. 3, Yuanqu Street, Nangang District, Taipei, Taiwan and has an office in Flushing, New York.

68. Upon information and belief, Keryx Biopharmaceuticals, Inc. ("Keryx") is a corporation incorporated under the laws of the State of Delaware, and has its principal, regular, and established place of business at 750 Lexington Avenue, New York, New York 10022.

## JURISDICTION AND VENUE

69. Jurisdiction of this Court arises under 28 U.S.C. § 1332, because the amount in controversy exceeds $75,000, exclusive of interest and costs, and the controversy is between a corporate entity located in New York state and a company located in a foreign state.

70. Venue is proper in this district under 18 U.S.C. § 1965 because Keryx is a corporation with headquarters in the city of New York.

## STATEMENT OF FACTS

### A. Background of Panion's Involvement with Ferric Citrate and the Development of Active Pharmaceutical Ingredient Technology (API)

71. Panion & BF Biotech, Inc. is company headquartered in Taiwan which actively licenses, develops, and manufactures pharmaceutical and cosmetic products. The company is also active in the creation, design, and supervision of clinical trials for its pharmaceutical products.

72. On July 20, 2001 Panion licensed technology related to the compound ferric citrate from Dr. Chen Hsing Hsu (hereinafter "Dr. Hsu"). Dr. Hsu is the inventor and owner of the U.S. Patent No. 5,753,706 (hereinafter "Hsu patent"), issued May 19, 1998 and entitled "Methods for Treating Renal Failure." This patent claims a treatment for persons suffering from

advanced end-stage kidney disease; the treatment involves the administration of ferric citrate to persons with that disease. While a United States patent has issued on this technology, patent applications have been filed in other foreign jurisdictions worldwide on the technology. Many of these applications are currently being prosecuted before their respective patent offices.

73. The Licensing Agreement executed between Panion and Dr. Hsu specifically encompassed development of an Oral Ferric Citrate Capsule by granting to Panion, exclusive rights to make, use, and sell the inventions of the aforementioned U.S. patent and its Taiwanese equivalent outside of the People's Republic of China. Panion further possessed rights for Investigational New Drug (IND) application No. 52,868 for "Oral Ferric Citrate Capsule", which was filed with the United States Food and Drug Administration (FDA) for the purpose of gaining FDA approval for the treatment contained in the Hsu patent.

74. The compound ferric citrate should not be administered to patients "as is." Commercially available chemical grade ferric citrate lacks rigorous quality control and must be purified through the removal of numerous impurities. At the beginning of the development of this project, Panion initially attempted to buy commercially available chemical grade ferric citrate and to purify it to pharmaceutical grade: because Panion's initial attempts were unsuccessful, Panion ultimately developed costlier and more demanding synthetic methods of purification. Panion has invested extensive research efforts in the synthetic process from the very beginning with highly purified raw starting materials and stringent process controls. The end result of the manufacturing process, i.e. the high quality pharmaceutical grade ferric citrate, is what is referred to by the parties as Active Pharmaceutical Ingredient (API). This API may thereafter be mixed with pharmaceutical grade fillers, and other pharmaceutical grade excipients, and put into capsules which will be administered to patients.

75. Since 2001 Panion has made extensive investments of time, resources, and expertise to establish a process for manufacturing ferric citrate into a Pharmaceutical Grade product in order to ensure pharmaceuticals which meets the highest quality and safety standards. The processes involved are highly controlled, implicating not only the beginning raw starting materials, but dictating the result to be achieved at each step of the manufacturing and control processes for production of the API. In contrast, chemical grade ferric citrate obtained from commercial sources of ferric citrate, and not suited for human consumption, is merely tested for appearance, solubility, and elemental analysis; indeed only one quality test – for elemental analysis – is performed on chemical grade ferric citrate. There are no tests performed on chemical grade ferric citrate for impurities such as heavy metals, microbial contaminants, yeast, mold, and organic solvents. In contrast, the necessary control tests for Panion's API include 20 separate Item Release Tests, with each Item Release Test consisting of many sub-tests. These control tests measure for various toxic substances such as heavy metals, microbial contamination, mold, yeast, and organic solvents, among others. They are used to strictly monitor and assure the quality of the API and any resulting product as well as to guarantee the safety of patients.

76. Independent of Keryx, Panion demonstrated the efficacy and dose-related increase in effect of the pharmaceutical grade ferric citrate in Phase II multi-national, multi-center clinical trials conducted both in five (5) clinical sites in the United States and one (1) site in Taiwan. Also independent of Keryx, Panion demonstrated to the United States Food and Drug Administration the safety of ferric citrate as compared to placebo capsules which contain no ferric citrate in its Phase II clinical study in the United States and Taiwan.

77. In addition, independently of Keryx, Panion has since 2001 actively worked with its contractors, BRI and BioVectra, to establish superior manufacturing processes for API. Indeed, BRI, located at 101-8898 Heather Street, Vancouver, British Columbia, Canada V6P 3S8, has been Panion's subcontractor for analytical services and Panion's primary provider of ferric citrate API since December 20, 2001. Additionally, BioVectra DCL ("BioVectra"), located at 16 McCarville Street, Prince Edward Island, Canada C1E 2A6, is a subcontractor of BRI which has likewise been involved in the manufacture of ferric citrate for Panion.

78. Based in large part upon the pharmaceutical grade developments Panion has made to ferric citrate, Panion has previously been able to protect their proprietary information and know-how by filing three (3) patents for the technology.

**B. The Panion-Keryx License Agreement**

79. Panion and Keryx entered into a License Agreement dated November 7, 2005 (hereinafter "License Agreement"). Panion retained all rights to the Asia-Pacific region under the License Agreement, with the exception of Japan, which was licensed to Keryx.

80. Under the License Agreement Panion licensed to Keryx the right "to develop, have developed, make, have made, use, have used, offer to sell, sell, have sold, import and export the Compound and Product," such Compound being "ferric citrate (PBF1681)", and such Product being "ferric citrate or any pharmaceutical product containing ferric citrate as an active ingredient, either alone or in combination with other active ingredients." The Compound in this context is referred to interchangeably by both parties in communications as Active Pharmaceutical Ingredient (API).

81. Pursuant to the License Agreement, Keryx's is required to purchase API exclusively from Panion absent certain circumstances not relevant to this action .

82. Pursuant to Section 7.7 of the License Agreement, Panion has the right to review and approve "all decisions and actions related to pharmaceutical development and manufacturing" of clinical supplies of API to be used by Keryx.

**C. Keryx Breached the License Agreement with Panion by Ordering API from Panion's Subcontractors and Failing to Pay Panion, and by Unilaterally Manufacturing Purported API That Did Not Meet Important Aspects of Panion's API Specifications, Without the Prior Review or Approval of Panion Required by the License Agreement.**

83. Panion introduced its manufacturing subcontractor, BRI, to Keryx for the purpose of providing Keryx with a better understanding of Panion's technology and manufacturing protocols but not for the purpose of permitting Keryx to manufacture API through Panion's own contractors in contravention of the provisions of the License Agreement.

84. In or about August 2006, Panion introduced BRI to Keryx and obtained from BRI a price quotation for the manufacture of API (according to Panion's specifications) which was provided to Keryx by Panion, informing Keryx that if this quotation was acceptable, Panion would provide a more formal quotation. Keryx accepted Panion's initial quotation, and in August 2006 Panion thereafter informed Keryx that Panion would obtain a formal quotation for 400 Kg of API (API that was to meet Panion's API specifications).

85. On August 24, 2006, as directed by Panion, Panion's subcontractor BRI forwarded to Keryx a quotation for manufacturing 400 Kg ferric citrate. Subsequent to the BRI quotation, Keryx, without authorization from Panion, caused BRI and others to manufacture four (4) separate batches of purported API, only one of which batches met Panion's API specification. At no time has Keryx paid or offered to pay to Panion the 15% profit margin (over Panion's subcontractor's price for the API) to which Panion is entitled under the License Agreement.

86. Panion's first awareness of and suspicions regarding Keryx's newly manufactured and unauthorized batches appeared on an e-mail from Keryx on January 10, 2007, requesting that Panion agree to a relaxation of five specifications for the manufacture of API. Among those five specifications, three specifications are related to materials which are potentially harmful when ingested in large quantity. As of January 10, 2007, Keryx had never disclosed to Panion the unauthorized specifications it had apparently used in manufacturing the four (4) batches, nor had Keryx sought or obtained the required review and approval for such batches.

87. The relevant harmful materials are as follows: first, the heavy metal arsenic, for which Keryx requested widening the range of acceptable arsenic levels by a factor of two - a change resulting in increased arsenic levels in API; second, the heavy metal mercury, for which Keryx requested widening the range of acceptable arsenic levels by a factor of 4.7 – a change resulting in increased mercury levels in API; and third, the organic solvent Acetone, for which Keryx requested widening the range of acceptable acetone by a factor of 4 – a change resulting in increased acetone levels in API.

88. Keryx specifically stated that, "We [Keryx] have decided to be a little more conservative in lowering the metals specifications because we have found that suppliers for the larger volumes of materials we will require cannot meet the ultra low levels available in early development." This and other communications from Keryx indicated to Panion that Keryx was apparently seeking to cut costs by altering the originally agreed manufacturing specifications of the API.

89. Keryx's January 10, 2007 email also raised Panion's suspicions that newly manufactured batches of API not meeting Panion's specifications had already been manufactured by Keryx without Panion's knowledge, review or approval.

90. In a January 11, 2007 e-mail, Panion informed Keryx that Panion was particularly concerned about Keryx's proposal to relax and broaden the carefully developed Panion API specification, without justification and without sound scientific support for each variation being proposed. As a result of Keryx's proposal to relax and broaden the specification, Panion requested on January 12, 2007 that Keryx provide batch records to Panion of any API already manufactured by Keryx.

91. On January 12, 2007, Keryx confirmed by email that new batches had been manufactured. In the email Keryx also admitted that it had previously, without any consultation with Panion, altered the manufacturing specifications, stating, "We [Keryx] have not yet changed the [Panion] manufacturing process. We [Keryx] did a feasibility evaluation for only one lot with the different dryer which has not able to reach our target goal. In the end, all batches were dried by the previous method."

92. On February 8, 2007, in view of continuing pressure from Keryx to change the API manufacturing specifications, Panion reminded Keryx that Panion was the party bearing liability for the FDA approval process, stating, "Panion is still the legal sponsor for the DMF [Drug Master File] and owner of the API and these rights HAVE NOT BEEN LICENSED to Keryx and the responsibilities of Panion to FDA HAVE NOT BEEN RELEASED." Panion further advised Keryx that Panion was not in agreement with altering the API specification, and requested a letter of release from Keryx from all legal consequences and liabilities were the specification to be changed.

93. On February 12, 2007 Keryx presented Panion with a release letter acknowledging that "Keryx has proposed a new set of specifications for the Drug Substance (API) which are different than those set by Panion during early stage development" and that

"Keryx acknowledges that this departure from the Panion original specifications is made on its own initiative and hereby releases Panion from all adverse legal and regulatory consequences derived from these changes in specifications." Due to its disapproval of Keryx's proposed departures, Panion did not sign or return the February 12, 2007 letter Keryx.

94. Panion received no response to its January 12, 2007 query for complete batch records. After more than a five month lapse of time with no response, Panion again requested API batch records from Keryx on July 30, 2007. Only on September 17, 2007 did Keryx ultimately send Panion certain records of the manufacture of the 4 batches that Keryx previously had manufactured without approval from Panion.

95. Throughout the existence of the License Agreement and until late summer of 2007, Keryx failed to provide Panion with progress reports on its activities as required by the License Agreement.

## CLAIMS FOR RELIEF

### FIRST CLAIM FOR RELIEF
**(Breach of Contract)**

96. All preceding paragraphs are incorporated herein by reference.

97. Panion placed Keryx on notice that Keryx's activities breached the License Agreement, and specifically Section 7.7 thereof, at least as early as October 31, 2007.

98. Keryx materially breached Section 7.7 of the License Agreement by purchasing API without paying to Panion the amounts due Panion for such purchase; by manufacturing purported API that did not meet the Panion API specification without prior approval from Panion; and by manufacturing and using batches of purported API which vary in composition from one another as to which Keryx has never requested or obtained Panion's required review and approval.

99. As a result of these breaches of contract, Panion has been damaged in an amount to be proven at trial, and is entitled to an injunction to restrain future breaches.

**SECOND CLAIM FOR RELIEF**
**(Breach of Implied Duty of Good Faith and Fair Dealing)**

100. All preceding paragraphs are incorporated herein by reference.

101. The License Agreement imposed upon Keryx the duty of good faith and fair dealing and requires that Keryx deal honestly and fairly with Panion in the performance of the terms of the License Agreement.

102. Keryx breached the duty of good faith and fair dealing by bypassing Panion and purchasing API without paying to Panion the amounts due Panion, by ordering and manufacturing 4 batches of API that did not meet Panion's specifications without the prior review and approval of Panion, and by manufacturing and using API with varying specifications without the prior review and approval by Panion.

103. As a result of this breach of the implied duty of good faith and fair dealing, Panion has been damaged in an amount to be proven at trial, and is entitled to an injunction to restrain future breaches.

**THIRD CLAIM FOR RELIEF**
**(Tortious Interference with Contract by Keryx)**

104. All preceding paragraphs are incorporated herein by reference.

105. Keryx knew of the existence of the business relationship between Panion and its subcontractors, BRI and BioVectra, and intentionally, wrongfully, and without justification interfered with Panion's subcontractor relationships with BRI and BioVectra by circumventing Panion in order to place orders of API with BRI, and causing said API to be manufactured using specifications unauthorized by Panion.

106. This interference by Keryx has harmed Panion and has entitled Panion to be compensated through payment of damages and through an injunction to restrain future breaches.

**FIFTH CLAIM FOR RELIEF**
**(Unjust Enrichment)**

107. All preceding paragraphs are incorporated herein by reference.

108. Keryx has used Panion's technology and produced unauthorized batches of API without paying Panion the amounts due Panion.

109. Keryx has been unjustly enriched by failing to pay to Panion the amounts due Panion.

**SIXTH CLAIM FOR RELIEF**
**(Breach of Fiduciary Duty)**

110. All preceding paragraphs are incorporated herein by reference.

111. Keryx owed fiduciary duties to Panion because Panion and Keryx engaged in a License Agreement, doing business in a manner in which Panion reposed trust and confidence in Keryx. Keryx's fiduciary duties to Panion included the duties of utmost care, good faith, loyalty, honesty, and full disclosure.

112. Keryx has breached these fiduciary duties by the acts and omissions described above detailing purchase of API and by unilaterally altering the manufacturing specifications of the Active Pharmaceutical Ingredient without the prior review or approval by Panion, thereby implicating safety and efficacy.

113. As a result of Keryx's breach of its fiduciary duties, Panion has been damaged in an amount to be determined at trial.

**PRAYER FOR RELIEF**

WHEREFORE, Panion respectfully requests judgment:

114. (a) that Keryx materially breached the License Agreement by purchasing API without paying to Panion the amounts due Panion for such purchase; by manufacturing purported API that did not meet the Panion API specification without prior approval from Panion; and by manufacturing and using batches of purported API which vary in composition from one another as to which Keryx has never requested or obtained Panion's required review and approval;

(b) that Keryx breached the implied covenant of good faith and fair dealing by purchasing API without paying to Panion the amounts due Panion for such purpose; by manufacturing purported API that did not meet the Panion API specification without prior approval from Panion; and by manufacturing and using batches of purported API which vary in composition from one another as to which Keryx has never requested or obtained Panion's required review and approval;

(c) that Keryx tortiously interfered with Panion's contractual relations with its subcontractors by engaging them to manufacture for Keryx, without payment to Panion, purported API that did not meet the Panion API specification, without prior approval from Panion; and by causing them to manufacture batches of purported API which vary in composition from one another, as to which Keryx has never requested or obtained Panion's required review and approval;

(d) that Keryx breached its fiduciary duties to Panion by purchasing API without paying to Panion the amounts due Panion for such purpose; by manufacturing purported API that did not meet the Panion API specification without prior approval from Panion; and by manufacturing and using batches of purported API which vary in composition from one another as to which Keryx has never requested or obtained Panion's required review and approval;

(e) enjoining Keryx from further manufacturing of causing to be manufactured on its behalf API without prior review and approval of such by Panion;

(f) enjoining Keryx from purchasing Clinical Supplies of the Compound (ferric citrate) during the Exclusive Supply Period other than directly from Panion at a 15% premium over Panion's manufacturing and procurement cost;

(g) enjoining Keryx from using any API heretofore manufactured by or for Keryx unless and until Panion has approved such.

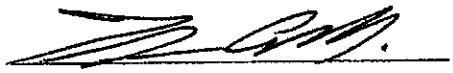
(h) awarding monetary damages to Panion in the amount of at least one million dollars ($1,000,000.00) or such greater amount to be proven at trial.

(i) awarding Panion its attorneys' fees and other legal costs in this case and its attorneys' fees and other legal costs for any legal action brought against subcontractors BRI/BioVectra and FluidAir/PharmPro for matters related to Keryx's contact with either subcontractor for unauthorized manufacture of ferric citrate, or "Product" or "Compound," or "Clinical Supplies of the Compound," as defined in the November 7, 2005 License Agreement.

(j) awarding such further and other relief as the Court deems just and proper.

Dated: New York, New York
January 14, 2008

Respectfully submitted,



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